DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 12, 2014

CONMED Corporation
Ms. Joy Lovett
Regulatory Affairs Specialist
11311 Concept Blvd
Largo, Florida 33773

Re: K142134
Trade/Device Name: C-Wire Double Ended Orthopedic Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: July 31, 2014
Received: August 6, 2014

Dear Ms. Lovett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142134

Device Name: C-Wire Double Ended Orthopedic Wires

Intended Use / Indications for Use:

C-Wires are single use devices. They are intended to be used by trained professionals for the purpose of bone fracture fixation. The C-Wires should only be used with wire drivers that are designed to drive wires having longitudinal flats.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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CONMED CORPORATION

510(k) Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, CONMED Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number K142134

Date Prepared: 5 September 2014

A. Submitter

ConMed Corporation, Largo
11311 Concept Boulevard
Largo, FL
Establishment Registration Number:

B. Company Contact

Joy Lovett
Regulatory Affairs Specialist
Phone: 727-399-5137
Fax: 727-399-5264

C. Device Name

Trade Name:	C-Wire Double Ended Orthopedic Wires
Common Name:	Fixation Wire
Classification Name:	Pin, Fixation, Smooth
Proposed Class:Device:	Class II
Product Codes:	HTY
Regulation:	21 CFR Part 888.3040

D. Predicate/Legally Marketed Devices

Device Name:	SMT Schilling Kirschner/Guide Wires, K100736
Company Name:	SMT Schilling Metalltechnik GmbH
510(k) #:	K100736

E. Device Description

The C-Wires are single use devices. They are intended to be used by trained professionals for the purpose of bone fracture fixation. The C-Wires should only be used with wire drivers that are designed to drive wires having longitudinal flats.

The intended use / indications statement for the C-Wires materially differs from that of the Schilling Kirschner/Guide Wires in that the C-Wire statement does not include a guidance function for insertion of implants into the skeletal system. CONMED manufactures a separate line of guidewires for this function. The

separation of these functions does not have an impact on the safety and effectiveness of the device.

F. Intended Use / Indications

The C-Wires are single use devices. They are intended to be used by trained professionals for the purpose of bone fracture fixation. The C-Wires should only be used with wire drivers that are designed to drive wires having longitudinal flats.

The intended use / indications statement for the C-Wires materially differs from that of the Schilling Kirschner/Guide Wires in that the C-Wire statement does not include a guidance function for insertion of implants into the skeletal system. CONMED manufactures a separate line of guide wires for this function. The separation of these functions does not have an impact on the safety and effectiveness of the device.

G. Summary of Technological Characteristics

The following table represents a summary of the technological characteristics of the ConMed C-Wire Double Ended Orthopedic Wires and the SMT Schilling Kirschner/GuideWires

	Proposed Device **CONMED C-Wire Double Ended Orthopedic Wires**	**Predicate Device** **SMT Schilling Kirschner/Guide Wires (K100736)**
Brief Description	C-Wire Double Ended Orthopedic Wires are single-use devices that are indicated for surgical repair of small bone trauma. The C-Wires provide mechanical stability during the natural bone healing process. Each wire is 5" (127mm) long, with each end ground to either a spade or trocar shaped tip. C-Wires are available in four different diameters (0.7mm, 0.89mm, 1.14mm and 1.57mm). The wires are made of 316LVM stainless steel.	Orthopaedic fixation pins and wires are metal pins for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeleton system. To ensure the multi-use of these devices, many different models are available. This differences can be as follows: Diameter: from 0.6 – 6.35mm Length, from 60 up to 500mm Tips: diamond or trocar point, round, flat, with or without 3- or 4-shank ends, with or without spherical shape. Surface: complete or partial smooth and/or threaded, with or without threading cutter.

	Proposed Device **CONMED C-Wire Double Ended Orthopedic Wires**	**Predicate Device** **SMT Schilling Kirschner/Guide Wires (K100736)**
Intended Use/Indications for Use	C-Wires are single use devices. They are intended to be used by trained professionals for the purpose of bone fracture fixation. The C-Wires should only be used with wire drivers that are designed to drive wires having longitudinal flats.	Orthopaedic fixation pins and wires are intended to perform as fixation and stabilization unit of bone fractures or as guidance at insertion of implants into the skeletal system.
Material	316LVM	316L
Conditions of Use	Operating Room in Hospital or Ambulatory Surgical Center for fracture fixation	Operating Room in Hospital or Ambulatory Surgical Center for fracture fixation or guide for implant
Scientific Technology	Metal rods inserted using powered handpieces	Metal rods inserted using powered hand pieces
Sterilization Method and SAL	Gamma Sterilization at a SAL of 10^{-6}	Gamma Sterilization at a SAL of 10^{-6}

Completed testing includes the following:

- Transportation
- Biocompatibility
- Sterilization
- Shelf-life

Functional testing on the C-Wires is not required as safety and effectiveness has been established through the following:

1. The device has been in continuous use for thirty-eight (38) years with few complaints regarding breakage, insertion or pull-out as detailed in Post Market Surveillance Reports.
2. The C-Wire is very similar to other wires cleared by FDA based on a comparison of intended use, engineering drawings, material, method of operation and shape/size. This similarity is documented in the Comparison Chart of Section 13 and summarized below for the predicate device, SMT Schilling Kirschner/Guide Wires (K100736).
3. Conformance to FDA standards related to pins and wires as well as other FDA recognized Standards governing aspects of product development and total life cycle.

H, Substantial Equivalence

The C-Wire Double Ended Orthopedic Wires have the same intended use, conditions of use, sterilization method, sterility assurance level and utilizes the same fundamental scientific technology as the predicate device, while raising no new issues of safety or effectiveness. Similarities of the two devices are demonstrated in

a comparison of the engineering drawings as well. Refer to Attachment 14-1. The C-Wire Double Ended Orthopedic Wires are therefore substantially equivalent to the SMT Schilling Kirschner/GuideWires cleared under K100736.

I. CONCLUSION

Based upon the testing and analysis performed, the C-Wire Double Ended Orthopedic Wire is as safe, as effective, and performs as well as the SMT Schilling Kirschner/Guide Wires (K100736)..